

Case Number:	CM15-0162760		
Date Assigned:	08/31/2015	Date of Injury:	03/21/2001
Decision Date:	10/05/2015	UR Denial Date:	08/07/2015
Priority:	Standard	Application Received:	08/19/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: California, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 63 year old female who sustained an industrial injury on March 21, 2001. The worker is employed as a school teacher. The accident was described as while taking toys out of a shed for the children to play with she lifted a bicycle out by the handle bars and the back of the bike swung around striking her left knee resulting in injury. A primary treating follow up visit dated March 20, 2015 reported subjective complaint of continues with right lower extremity pain and occasional buckling and swelling causing increased pressure on the left knee. There is note of having increased pain at nit with interrupted sleep. In addition, she states having had a Synvisc injection previously that offered a 60-70 % reduction in symptom and the ability to walk for a year. Objective assessment found bilateral knees with well-healed surgical scars of the left knee; tenderness to palpation over bilateral medial and lateral joint lines; mild generalized swelling of the right knee. She was diagnosed with right knee tricompartmental osteoarthritis with patella femoral arthralgia, and status post left total knee replacement in 2005. The plan of care noted pending response regarding authorization to administer another Synvisc injection; and continue utilizing the transcutaneous nerve stimulator unit. Current medication regimen consisted of: Ultram ER, Fexmid. A primary follow up on June 02, 2015 reported subjective complaint of still experiencing the right knee buckling. A Synvisc injection administration is still pending authorization. She states her symptom is severe in intensity. She is deemed temporarily totally disabled for 6 weeks. No change in plan of care noted. Follow up dated July 20, 2015 reported subjective complaint of now with left knee pain secondary to right knee issue. Objective assessment showed the left knee with well-healed surgical scars, swelling

at the medial joint line with tenderness to palpation. There is a positive McMurrays' on the right knee with crepitus and patellofemoral arthralgia noted. The plan of care noted performing an ultra sound of the right knee in consideration of right knee surgery; recommendation to obtain a right knee sleeve for support while ambulating; prescribed Anaprox DS.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

One (1) Bionicare knee system brace for the right knee: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 340.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, BioniCare knee device.

Decision rationale: Per the ODG guidelines regarding the BioniCare knee device: Recommended as an option for patients in a therapeutic exercise program for osteoarthritis of the knee, who may be candidates for total knee arthroplasty (TKA) but want to defer surgery. See also TENS (transcutaneous electrical nerve stimulation). This device received FDA approval as a TENS device, but there are additional claims of tissue regeneration effectiveness and studies suggesting the possibility of deferral of TKA with use of the BioniCare device. Compared with TENS there are differences in the electrical signal (having a monophasic pulsed time varying waveform versus biphasic with TENS), electrical stimulus (having signal strengths that the patient cannot detect), FDA indications for use (includes overall improvement of knee osteoarthritis), mechanisms of action (includes cartilage stimulation), onset and duration of action (analgesia is delayed but the effect persists longer), route of administration (only for use overlying the osteoarthritic knee), hours of use (6-10 hours/day while sleeping, versus 10-30 minutes/day for TENS). The higher quality studies are summarized below. Improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation using the Bionicare device is effective for treating OA of the knee. (Zizic, 1995) After 4 years 65% of the Bionicare group had deferred TKA versus 35% of the group with no treatment, but the Bionicare cohort may have delayed surgery because they were instructed by a nurse practitioner to use the Bionicare device for 8 hours per day, suggesting that it would be a cure. (Mont, 2006) The Bionicare device successfully attenuated knee OA symptoms in patients who had failed non-surgical therapy. Less than 250 hours of therapy provided relief, but improvement increased in a dose-response manner after 750 hours of cumulative use. (Farr, 2006) Bionicare treatment provided superior outcomes between baseline and 3-month follow-up measurements. The percent of patients who improved by more than 50% was 38.5 active vs 5.3 placebo in patient global, 43.6 vs 15.8 in patient pain, and 23.1 vs 5.3 in total WOMAC. (Garland, 2007) The documentation submitted for review does not indicate that the injured worker is participating in a therapeutic exercise program or is a candidate for total knee arthroplasty. As there is no indication for the device, the request is not medically necessary.

One (1) right knee sleeve: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 340.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, Knee brace.

Decision rationale: Per the ODG guidelines regarding knee brace: Recommended as indicated below. Recommend valgus knee braces for knee OA. Knee braces that produce a valgus moment about the knee markedly reduce the net knee adduction moment and unload the medial compartment of the knee, but could be impractical for many patients. There are no high quality studies that support or refute the benefits of knee braces for patellar instability, ACL tear, or MCL instability, but in some patients a knee brace can increase confidence, which may indirectly help with the healing process. In all cases, braces need to be used in conjunction with a rehabilitation program and are necessary only if the patient is going to be stressing the knee under load. Criteria for the use of knee braces: Prefabricated knee braces may be appropriate in patients with one of the following conditions: 1. Knee instability, 2. Ligament insufficiency/deficiency, 3. Reconstructed ligament, 4. Articular defect repair, 5. Avascular necrosis, 6. Meniscal cartilage repair, 7. Painful failed total knee arthroplasty, 8. Painful high tibial osteotomy, 9. Painful unicompartmental osteoarthritis, 10. Tibial plateau fracture. Custom-fabricated knee braces may be appropriate for patients with the following conditions which may preclude the use of a prefabricated model: 1. Abnormal limb contour, such as: a. Valgus [knock-kneed] limb; b. Varus [bow-legged] limb; c. Tibial varum; d. Disproportionate thigh and calf (e.g., large thigh and small calf); e. Minimal muscle mass on which to suspend a brace; 2. Skin changes, such as: a. Excessive redundant soft skin; b. Thin skin with risk of breakdown (e.g., chronic steroid use); 3. Severe osteoarthritis (grade III or IV); 4. Maximal off-loading of painful or repaired knee compartment (example: heavy patient; significant pain); 5. Severe instability as noted on physical examination of knee. The documentation submitted for review contains no recent findings of right knee instability or any other indication for knee sleeve. The request is not medically necessary.

One (1) diagnostic ultrasound study of the right knee: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, Ultrasound, diagnostic.

Decision rationale: Per the ODG guidelines with regard to ultrasound: "Recommended as indicated below. Soft-tissue injuries (meniscal, chondral surface injuries, and ligamentous disruption) are best evaluated by MR. In addition to MR, sonography has been shown to be diagnostic for acute anterior cruciate ligament (ACL) injuries in the presence of a hemarthrosis or for follow-up. (ACR, 2001) See also ACR Appropriateness Criteria." Ultrasound is only

recommended in limited cases for knee joint injections. Diagnostic ultrasound has been shown to be diagnostic for acute anterior cruciate ligament (ACL) injuries in the presence of hemarthrosis or for follow-up. Soft-tissue injuries are best evaluated by MR. As ultrasound is not indicated, the request is not medically necessary.